Risk Assessment
Importation of Feeder Cattle to the United States From Australia

Diseases of Concern:
Bluetongue, Akabane, Aino, Bovine Ephemeral Fever, Babesiosis, Brucellosis, Tuberculosis

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United States Department of Agriculture
Animal and Plant Health Inspection Service
Policy and Program Development
Veterinary Services

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Introduction and Objective

The Animal and Plant Health Inspection Service (APHIS) and the Australian Quarantine and Inspection Service (AQIS) recently negotiated protocols defining provisions for exporting Australian feeder cattle to the United States. This report evaluates the risk of transmitting bluetongue (BLU), akabane, aino, bovine ephemeral fever, babesiosis, brucellosis, and tuberculosis while the restrictions of the negotiated protocols are being observed.

The approaches taken for individual diseases are the following:

1. The assessment of BLU is quantitative and based on probability estimates. Risk is evaluated with and without compliance with a 60-day pre-embarkation quarantine. The assessment is based on data describing the duration of viremia and on the assumption that cattle may originate and be exported from any region of Australia, including regions affected with BLU. "The Protocol for Importing Feeder Cattle from Australia" is included as Appendix A.

2. Separate risk assessments are not performed for akabane, aino, and bovine ephemeral fever. The assessments for these diseases are conducted solely under mitigating effects specified by the import protocol in Appendix A and include the mitigating effects of the 60-day quarantine. Like the assessment for BLU, the assessments for akabane, aino, and babesiosis are based on the assumption that cattle may originate and be exported from any region of Australia, including regions affected with those diseases. Data are cited to indicate that the duration of viremia for these diseases is shorter than that for BLU. Assuming that the quarantine reduces the risk of BLU to an acceptable level, the risk of introducing akabane, aino, and bovine ephemeral fever should also be reduced to an acceptable level.

3. The risk of introducing babesiosis is considered acceptable because the protocol requires standard mitigations for this disease.

4. The evaluations for brucellosis and tuberculosis are based on APHIS risk assessments performed before generation of this report. These assessments, which conclude that Australia is free from both diseases, are included as Appendices B and C.

5. The risk of importing Australian cattle into the United States through Mexico is compared with the risk from direct shipment. Because transit through Mexico takes longer than direct shipment from Australia, the risk of transshipment of cattle through Mexico is considered less than the risk of direct shipment from Australia.

Import protocols

The import protocols for cattle have restrictions intended to mitigate the risk of Australian cattle introducing animal diseases into the United States. A key element of the protocols is a 60-day pre-embarkation quarantine. In addition, the protocols require the U.S. importer to obtain an import permit specifying a USDA-approved import quarantine feedlot as the destination, and the animals must be accompanied by an official health certificate from Australia. The certificate must verify that the animals were born and raised in Australia and have been in no other country. Finally, the animals must be uniquely identified by an AQIS number or microchip. These requirements provide a mechanism to verify the quarantine conditions.

Importing Australian cattle through Mexico

An additional issue addressed in this report is importing Australian cattle into the United States through Mexico (see ABC News Brief, Appendix D). United States producers objected recently to the practice of importing Australian cattle into the United States through Mexico. The producers' concerns are addressed by comparing risk factors associated with importing cattle into the U.S. directly from Australia to approved feedlots in this country with those associated with trans-shipment of cattle through Mexico.

Bluetongue: Relevant Epidemiological Considerations for BLU

BLU Regions in Australia

The Australian Quarantine and Inspection Service demonstrated to APHIS that Australia is divisible into two regions based on BLU incidence. Data supporting BLU regionalization of Australia were generated by monitoring sentinel herds throughout the country for BLU viremia and vector fauna in the region (Melville et al. 1996a, b; Gibbs and Homan 1992). The data demonstrate that far northern and eastern regions contain a belt in which BLU infection occurs in sheep and cattle. Infection was not detected in the remainder of the country. AQIS has stated that it will provide certification that the defined region is BLU-free (AQIS 1998).

BLU Epidemiology

Bluetongue is caused by an arbovirus that naturally infects domestic and wild ruminants, camelids, and some other species. The BLU virus is endemic in the United States and Australia, although the virus serotypes observed and the competent vectors differ in the two countries. The virus moves among vertebrate hosts through the bite of a midge, one of the *Culicoides* species. Disease distribution is influenced by seasonal considerations, environmental factors, the presence of competent vectors, and the presence of pathogenic serotypes of the virus. Disease occurs primarily at those times of the year and in those environments that provide a conducive habitat for a competent vector. The virus apparently requires alternate cycles of virus replication in

vertebrates and invertebrates to persist (Barratt-Boyes and MacLachlan 1995; Gard and Melville 1992; OIE 1998; MacLachlan 1994; Melville et al. 1996a; Pearson et al. 1992; Tabachnick 1996).

Production of disease requires a minimum number of competent midges, a pathogenic serotype of the virus, a minimum level of viremia, and a susceptible host (OIE 1998). An adequate number of competent midges capable of transmitting sufficient levels of virus to cause infection in cattle is present in Australia's BLU-affected region. This is demonstrated indirectly by the presence of BLU viremia in sentinel cattle herds monitored by the National Arbovirus Monitoring Program (AQIS 1998; Gard and Melville 1992; NAMP 1997-1998; NAMP 1996-1997).

Virus infection does not result in clinical disease in all species. Infected cattle do not demonstrate clinical signs or disease. However, infected cattle may serve as reservoirs from which competent midges become infected. The insects can then transmit the virus to susceptible species such as sheep and wild deer that may develop clinical disease, perpetuate the infection, or both (OIE 1998).

BLU disease has not been observed anywhere in Australia, in either cattle or sheep. Furthermore, BLU has never been diagnosed in commercial flocks of any species in Australia (AQIS 1998; OIE 1998). The reason for this is not clear, as BLU-seropositive sheep and goats were identified in the BLU virus-endemic areas of northern and central Queensland (Flanagan et al. 1995). At least one of the virus serotypes associated with the region produced clinical signs in sheep experimentally inoculated with infected sheep blood (Hooper, Lunt, and Stanislawek 1996). Additional experimental data suggest that Australian BLU serotypes infecting cattle cause disease and death in sheep (Johnson, et al. 1992). The extent of clinical disease in this study varied with the serotype and ranged from mild clinical signs (fever) to death.

Vector Competence and Serotype

Vector competence and serotype pathogenicity are extremely variable. Not all *Culicoides* vector species are equally competent to transmit all BLU serotypes, and not all serotypes are equally pathogenic. Vector competence for a particular serotype is often identified through regional concurrence of the serotype and vector, and vector competence varies with disease serotype (OIE 1998). A comparison of the vectors and BLU serotypes demonstrated that there is no overlap between either the vectors or the BLU serotypes occurring in the United States and Australia (Tabachnick 1996; Gard and Melville 1992).

Four *Culicoides* species are recognized as vectors of BLU in Australia. These are *C. brevitarsis, C. wadai, C. fulvus,* and *C. actoni* (AQIS 1998). These have been associated with 8 Bluetongue serotypes (i.e., BLU 1, 3, 9, 15, 16, 20, 21, and 23). Both vectors and virus are localized primarily to the far north regions and isolated areas in Queensland and in New South Wales (AQIS 1998; NAMP 1995-96). They have not been detected in Australia's BLU-free region (AQIS 1998).

Some Australian vectors have been characterized as fecal patty breeders (Gard and Melville 1992; Doyle 1992). However, because all feeder cattle imported into the United States from Australia will be quarantined for 60 days in a vector-free area, this should not be a problem. Moreover, APHIS has no evidence to indicate that vectors have migrated as a result of international trade. Some analysts believe that trading patterns in animals have probably contributed little to the geographic distribution of BLU viruses (Gibbs 1992; Gibbs and Greiner 1994).

In contrast to the vectors in Australia, vectors of BLU in the United States belong to a *C. varipennis* complex. This complex represents a group of midges apparently composed of three species or subspecies that vary in their competence (Tabachnick 1996). The BLU serotypes 2, 10, 11, 13, and 17 are the only ones known to exist in the United States (Tabachnick 1996).

A relatively extensive literature survey and discussions with BLU experts yielded no information regarding the competence of Australian vectors for U.S. serotypes or vice versa**.**

Hazard identification

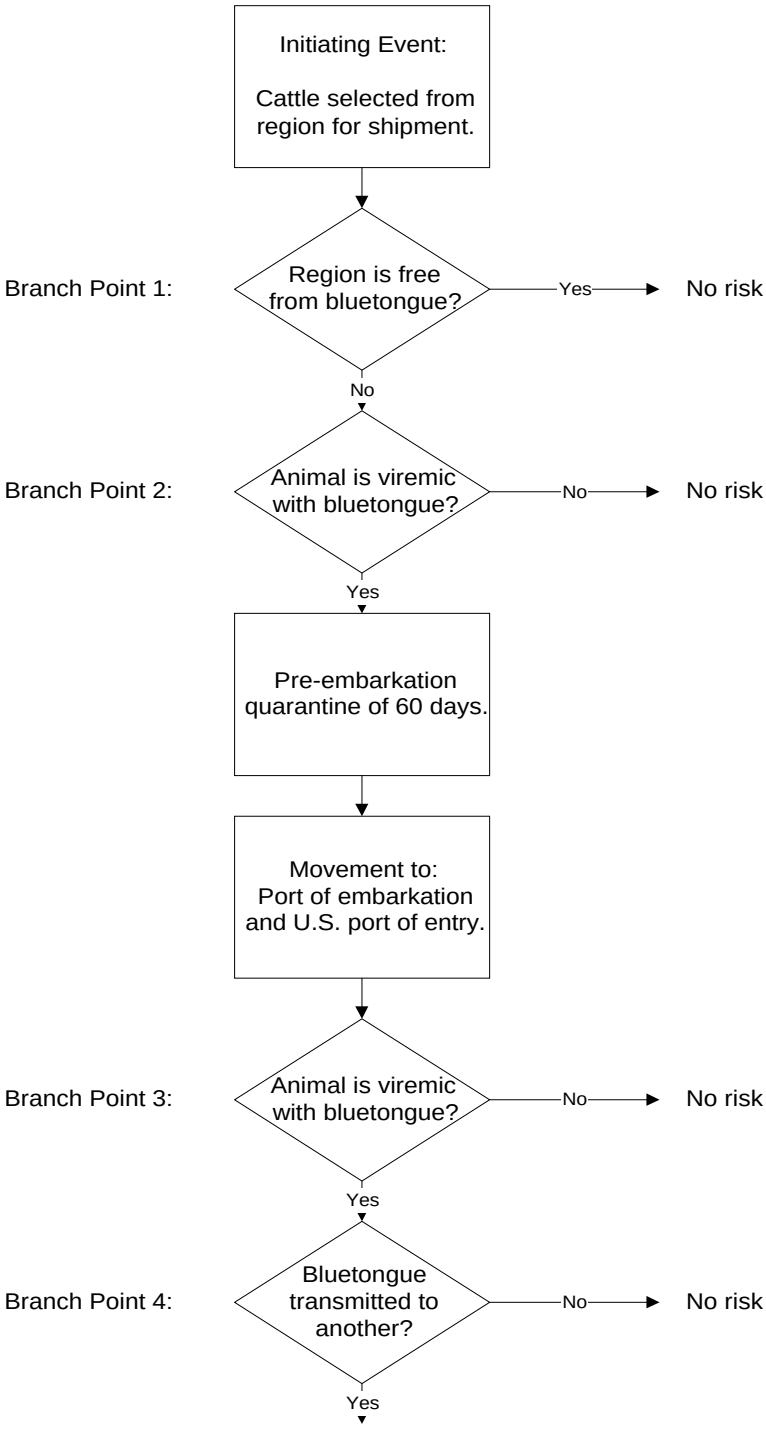
If competent vectors are present, importating BLU viremic feeder cattle into the United States may introduce BLU virus and clinical disease into U.S. sheep, wildlife, or both.

BLU Risk Assessment

The risk assessment estimates the probability that cattle legally exported from Australia will introduce BLU disease into the United States. A scenario tree (Figure 1) describes the sequence of events that must occur for BLU to be introduced. The assessment begins by estimating the probability that a viremic animal from the BLU-affected region of Australia will enter the pre-embarkation quarantine facility. Second, the assessment determines the probability that such animals will remain viremic throughout the quarantine period and the period of transport to the United States. The approach depends on epidemiological data since there is no testing requirement to detect disease in imported cattle.

Australian Feeder Cattle - March 13, 2000

Figure 1 - Scenario Tree:
Export of feeder cattle from Australia to the United Stateswhere disease of concern is bluetongue.



Initiating Event

The initiating event for this tree is the selection of feeder cattle from Australia for shipment to the United States.

Branch Point 1

Cattle may originate from any region of Australia. They may be selected for export from a region in Australia specified by AQIS as continuously free from BLU (BLU-free) or they may be selected from the region that is not free (BLU-affected). These regions are defined in documentation Australia provided to APHIS supporting the disease status of the regions. Australia's data defining these regions are based on monitoring of sentinel animal herds throughout the country and insect monitoring. Since 1985, viremia has been assessed using embryonated egg isolation (AQIS 1998).

The Animal and Plant Health Inspection Service has evaluated AQIS's data. The evaluation is included as Appendix E.

Branch Point 1 of the scenario tree separates cattle into those selected from the BLU-affected and the BLU-free region. The APHIS risk assessment is limited to animals originating from the affected region, since APHIS has previously evaluated risk of animals originating from the regions AQIS has identified as free from BLU (Appendix E).

The Australian Quarantine and Inspection Service estimates that no cattle will be exported from Australia to the United States in the year 2000 (Personal Communication, Oliver 1999). Projections for the number of cattle to be exported in subsequent years range from 40,000 to 50,000. AQIS projects that all of the exported animals will originate from the BLU-free zone for several years. Therefore, the risk of importing BLU is negligible for several years (Personal Communication Oliver 1999).

In future years, AQIS projects that up to 150,000 to 200,000 cattle will be exported to the United States. Approximately 30,000 of these may originate from the BLU-affected zone (Personal Communication, Oliver, 1999). Risk is estimated based on the annual export of these 30,000 cattle.

The cattle will originate from BLU-affected areas in four States: New South Wales (NSW), Northern Territory (NT), Queensland (QLD), and Western Australia (WA). Origin of the 30,000 animals as a function of time (in months) is described in Table 1 for the BLU-affected areas in each of these four States.

Table 1. Projected Exports from BLU Affected Zones

	A	B	C	D	E	F
435	**Exports Per Year From Affected Zones**					
436		NSW	NT	QLD	WA	Total
437	Jan	833.3333	0	714.2857	0	1547.619
438	Feb	833.3333	0	714.2857	0	1547.619
439	Mar	833.3333	0	714.2857	0	1547.619
440	Apr	833.3333	0	714.2857	0	1547.619
441	May	833.3333	0	714.2857	0	1547.619
442	Jun	833.3333	0	2000	1000	3833.333
443	Jul	833.3333	0	2000	1000	3833.333
444	Aug	833.3333	0	2000	1000	3833.333
445	Sep	833.3333	0	2000	1000	3833.333
446	Oct	833.3333	0	2000	1000	3833.333
447	Nov	833.3333	0	714.2857	0	1547.619
448	Dec	833.3333	0	714.2857	0	1547.619
449	Total	10000	0	15000	5000	**30000**

Branch Point 2 (Animal selected for export quarantine is viremic with BLU)

An animal entering the pre-embarkation quarantine from the BLU-affected region may be viremic or nonviremic. The underlying question posed at Branch Point 2 is: Of all the cattle from Branch Point 1 coming from the affected region, what is the probability that the number of ***viremic*** cattle entering pre-embarkation quarantine is 0, 1, 2, 3,... , ... n_2?

The answer to this question is provided by the binomial probability distribution,

$$P(X=k) = (n_2!/(k!(n_2-k)!))p_2^{k} (1-p_2)^{n2-k}$$

where n_2 is the number of cattle from the affected region, exported per year to the United States.

p_2 is the prevalence

k is the number of viremic cattle entering pre-embarkation quarantine (0, 1, 2, 3, ... n_2).

Although the data supplied by AQIS report incidence, prevalence is used for the p_2 value for the preceding binomial distribution because the binomial requires prevalence as the input value. For reference, prevalence is the probability or proportion of cattle with the disease at any point in time, whereas incidence is the probability that an animal will develop the disease over time. Conversion of the incidence data provided by AQIS to prevalence values is discussed in detail in Appendix G, section I. The prevalence values obtained are reported in Table 8, which appears in Appendix G, section I: Conversion of Incidence to Prevalence.

The probability values for Branch Point 2, which are dependent on the number of viremic animals entering the facility, must be combined with those estimated for Branch Point 3 to estimate a final probability. The approach to estimating probability values for Branch Point 2 is discussed in Appendix G, section II.

Branch Point 3

The question asked at Branch Point 3 is: Of all the ***viremic*** cattle entering the pre-embarkation quarantine from Branch Point 2 (0, 1, 2, 3, ..., ... n_3), what is the probability that no cattle are viremic when arriving at the U.S. port of entry? That question is answered by the following binomial probability distribution:

$$P(X=k) = (n_3!/(k!(n_3-k)!))p_3^{k} (1-p_3)^{n3-k}$$

where n_3 is the number of ***viremic*** cattle entering the pre-embarkation quarantine from Branch Point 2 (0, 1, 2, 3 ... ... n_3),
p_3 is the probability that the animal is viremic after the onset of infection ***and*** after time in pre-embarkation quarantine ***and*** time traveling to U.S. port of entry, and
k is 0, the number of viremic cattle entering U.S. port of entry.

The total time from the onset of infection until entering the U.S. port of entry (t4), a parameter used to estimate p_3, is equal to the sum of the following:

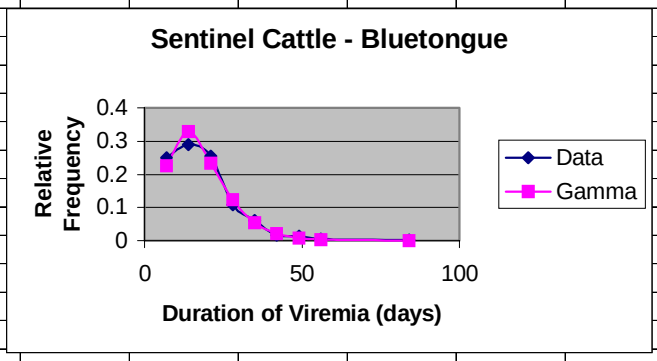
1. The number of days that an animal has been viremic upon entry into preembarkation quarantine (t1); .
2. The number of days of preembarkation quarantine (t2); and
3. The number of days of travel from the end of pre-embarkation quarantine until entering U.S. port of entry (t3).

We identify an appropriate probability distribution for the duration of viremia to estimate t1. The distribution is described in Table 2, which reproduces the duration data provided by AQIS and reported in Table 7 (see Appendix G, section I). The data are expressed as the frequency of cattle that is viremic at different times after infection and are reported as a function of duration of viremia in both weeks (column A) and days (column B). These data are reported graphically within the table in the box entitled, “Sentinel Cattle - Bluetongue.”

Table 2. Probability Distribution Describing Viremia

Using the software, "Best Fit" of Palisade Corporation, we determined that the gamma distribution with alpha parameter 3.51958 and beta parameter 5.118425 displays the most

	A	B	C	D	E	F	G	H	I	J	K
136			**Number of Cattle Showing Viremia**								
137	Duration of Viremia		Relative	Normalized							
138	Weeks	Days	Fregency	Gamma							
139	1	7	0.249476	0.225828							
140	2	14	0.289308	0.329839							
141	3	21	0.255765	0.233364							
142	4	28	0.109015	0.122711							
143	5	35	0.060797	0.054842							
144	6	42	0.016771	0.022114							
145	7	49	0.012579	0.008306							
146	8	56	0.004193	0.002962							
147	12	84	0.002096	3.46E-05							
148	Total		1	1							
149											
150											
151											



appropriate fit to the duration of viremia data. The graphical representation shown in Table 2 demonstrates the fit of the data to the gamma distribution. This gamma distribution describes the probability that an animal remains viremic x number of days after the onset of infection. It has a mean of 18.01 and standard deviation of 9.60.

The number of days since the onset of viremia (t1) must be estimated for each animal that is viremic upon entering the pre-embarkation quarantine. That number of days is determined from the descending cumulative distribution of gamma distribution illustrated in Table 2. An illustration of this type of descending cumulative distribution is shown in Figure 5 as part of the justification fur using this approach (Appendix G, section II: Stage of Viremia). The actual distribution for the data is not presented.

A probability distribution for the duration of viremia is defined and used to estimate t1. This distribution addresses the fact that not all viremic animals will enter quarantine at the same stage of viremia, i.e., at the same time after initial infection. Some will enter early after infection; others may enter in the middle of or toward the end of the viremic period.

The time in quarantine (t2) is 60 days. The time from end of quarantine to entry into the U.S. is t3.

The distribution of the stage of viremia for animals entering the pre-embarkation quarantine will influence the probability that an animal remains viremic at the end of quarantine and upon entry to

the United States. Adding the values in days for t1 and t3 to the 60 day quarantine period (t2) provides an estimate for the total time from onset of infection until arrival at U.S. port of entry. Table 3 describes the methods used to estimate the total time from the onset of infection until the animal enters the United States.

Table 3. Time from Onset of Infection Until Entry into the United States

	A	B	C	D	E	F	G	H	I	J	K	L	M
153	Distribution of time from onset of infection until entering quarantine (days):								13.98827	=RiskGeneral(1,145,C163:C191,			
154	Time in pre-embarkation quarantine (days):								60	J163:J191)			
155	Time from end of quarantine to entering U.S. port of entry (days):								25	=RiskUniform(20,30)			
156													
157	Total time from onset of infection until entering U.S. port of entry (days):								98.98827	=I153+I154+I155			

The values shown in Column I are the expected values in days:

A. The time from the onset of infection until the animal is quarantined (13.98827 days) is obtained using the @Risk probability distribution function, RiskGeneral. Parameters associated with this function are a minimum of 1 day and a maximum of 145 days (K153).

B. The time of quarantine (I154) is fixed at 60 days by the protocol.

C. The time for movement to the port of embarkation and the U.S. port of entry (I155, 25 days) is obtained using the @Risk probability distribution function RiskUniform. Parameters associated with this function are a minimum of 20 days (K155) and a maximum of 30 days (K155). APHIS uses a uniform distribution that assumes there is an equal probability of any number of days between 20 and 30, based on information provided by AQIS (Personal Communication , Oliver 1999).

D. The total time from the onset of infection until the animal enters the U.S. port of entry (t4, 98.98827 days, I157) is the sum of these three estimates (t1 plus t2 plus t3).

For Branch Point 3, given that the animal is viremic when entering the pre-embarkation quarantine, the probability, p_3, that an animal is viremic upon arrival at the U.S. port of entry is determined from the descending cumulative gamma distribution of the curve presented in Table 2. The probability is the value on the y axis of the descending cumulative gamma distribution corresponding to the sum (t4) of t1, t2, and t3 (t4 graphed along x axis, actual graph not shown). A further illustration of this concept is presented in Appendix G, section II.

Estimation of Joint Probabilities

The methods used to determine the probability that no viremic cattle are imported to the U.S. ***during the year*** link the probability for Branch Point 2 (probability that k cattle are viremic upon entering the pre-embarkation quarantine) and the probability for Branch Point 3 (probability that, given k viremic animals entering the pre-embarkation quarantine, zero animals are viremic after the onset of infection ***and*** after time in pre-embarkation quarantine ***and*** time traveling to the U.S. port of entry). The formula, $1-(p_2*p_3))^n$ was used to calculate the joint probabilities. Use of this formula is justified in Appendix G, section III: Joint Probabilities.

Table 4 shows expected values for the probability of importing no viremic cattle (zero) into the United States during the year. Values entered into the formula include the prevalence values of p_2 for each State and month reported in Table 8 (see Appendix G, section I). The values of p_3 are the probability values defined in the discussion of Table 2 using the cumulative distribution in Figure 5 (located in Appendix G, section II) and calculated using the total time from onset of infection until the animal passes through the U.S. port of entry (Table 3) and the values of n reported previously (Table 1).

Table 4. Probability of Importing No Viremic Cattle into the United States

	A	B	C	D	E	F	G	H
467	**Probability of 0 viremic cattle imported to U.S.**							
468		NSW	NT	QLD	WA	Total		
469	Jan	0.999564	1	0.998297	1	0.997863		
470	Feb	0.998793	1	0.998695	1	0.997489		
471	Mar	0.997815	1	0.997965	1	0.995784		
472	Apr	0.997269	1	0.997164	1	0.994441		
473	May	0.99812	1	0.997459	1	0.995584		
474	Jun	0.999252	1	0.993612	0.998332	0.991213		
475	Jul	0.999696	1	0.995867	0.998519	0.994091		
476	Aug	1	1	0.995715	0.998411	0.994133		
477	Sep	1	1	0.997553	0.9994	0.996954		
478	Oct	1	1	0.998352	0.998727	0.997082		
479	Nov	1	1	0.999403	1	0.999403		
480	Dec	0.999671	1	0.9993	1	0.998971		
481	Total	0.99022	1	0.969792	0.993407	**0.953977**		
482								
483	Probability > 0 viremic cattle imported to U.S. during year:						0.046023	=1-F481

The product of all the individual values or "cells" for each State and month (the estimated probability that no animal imported from any State during any month is viremic at the U.S. port of entry) is 0.953977 (F482). One minus this value represents the probability that one or more

viremic cattle are imported into the United States during the year. This probability is 0.046023 (G483).

Probability of Importing No Viremic Cattle During a Specified Period of Years

The most relevant question to address next is: What is the probability that no viremic cattle will arrive at the U.S. port of entry ***during a period of years*** of importing cattle from BLU-affected zones (0, 1, 2, 3 ... ... m)? The question may be answered using the following binomial probability distribution:

$$P(X=j) = (m!/(j!(m-j)!))r^j (1-r)^{m-j}$$

where m is the number of years during which 30,000 cattle are exported each year from the BLU-affected zones (0, 1, 2, 3 ... ... m),
r is the probability that > 0 viremic animals will be imported to the United States each year,
j is 0, the number of years that > 0 viremic animals will be imported to the United States.

When j=0, the binomial probability formula simplifies to:

$$P(X=0) = (1-r)^m$$

This formula is used to calculate the probability values over a 50-year period for both importing zero viremic cattle (1-r, values in Table 5, column B) and one or more viremic cattle (r, values in Table 5, column F). The probabilities are generated with the @Risk software of Palisade Corporation to perform simulations with samples taken from probability distribution functions defined in the Excel Model. Some of these values are reported. However, for simplicity, Rows 501-530 (representing years 11-40) are not.

The remaining input values for the formula are described elsewhere in this report. The value of r is reported previously in Table 4 (G483). The values of m appear in column A.

Table 5: Probability of Importing Viremic Cattle into the United States

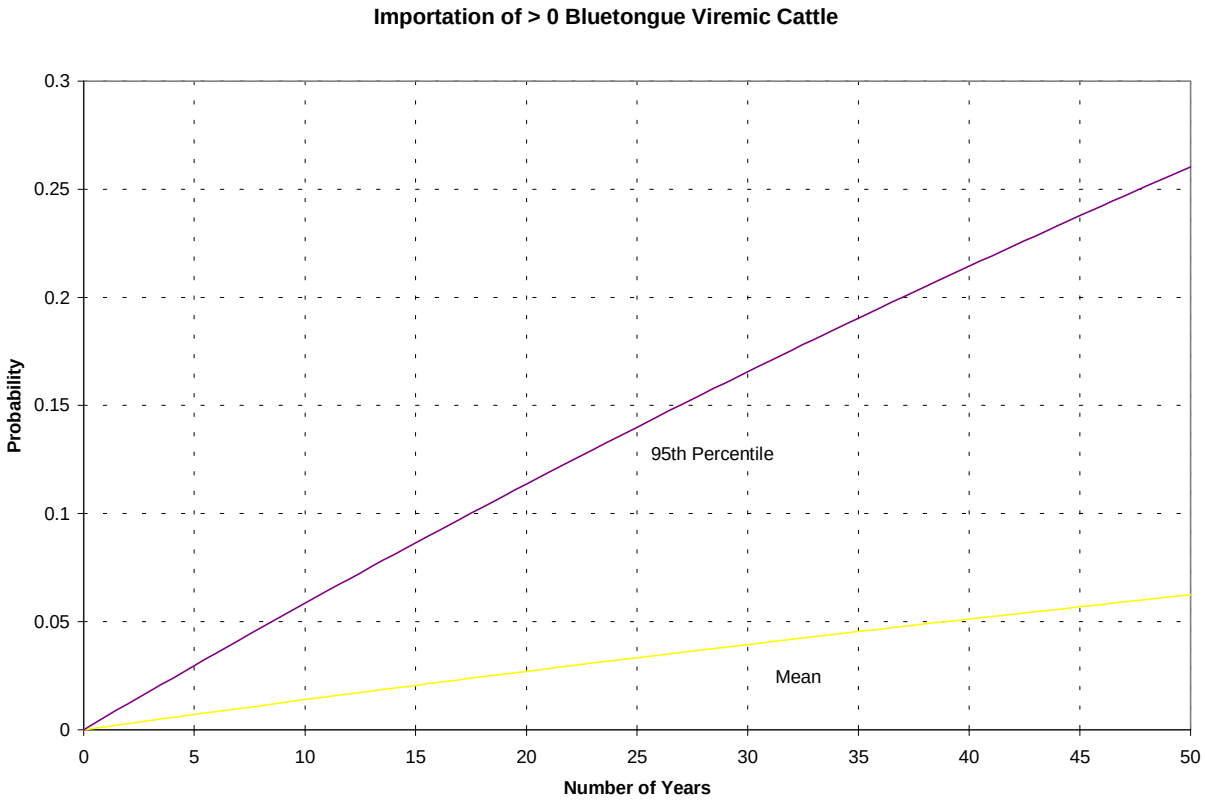
	A	B	C	D	E	F	G
487	**Number of Years Importing Cattle to U.S.:**						
488		Probability of Importing Viremic Cattle					
489	Years	0				> 0	
490	0	1	=(1-G483)^A490			0	=1-B490
491	1	0.953977	=(1-G483)^A491			0.046023	=1-B491
492	2	0.910071	=(1-G483)^A492			0.089929	=1-B492
493	3	0.868187				0.131813	
494	4	0.82823				0.17177	
495	5	0.790112				0.209888	
496	6	0.753748				0.246252	
497	7	0.719058				0.280942	
498	8	0.685965				0.314035	
499	9	0.654394				0.345606	
500	10	0.624277				0.375723	

For simplicity, results for years 11-40 (rows 501-530) are not presented.

	A	B	C	D	E	F	G
531	**41**	**0.144893**				**0.855107**	
532	**42**	**0.138224**				**0.861776**	
533	**43**	**0.131863**				**0.868137**	
534	**44**	**0.125794**				**0.874206**	
535	**45**	**0.120004**				**0.879996**	
536	**46**	**0.114481**				**0.885519**	
537	**47**	**0.109212**				**0.890788**	
538	**48**	**0.104186**				**0.895814**	
539	**49**	**0.099391**				**0.900609**	
540	**50**	**0.094817**				**0.905183**	

The probability of importing one or more viremic cattle (Table 5, column F) during a period of years may be the most relevant information for APHIS decision makers to use in assessing risk. These data are presented graphically in Figure 2, which reports the mean probability that one or more viremic cattle will enter the United States as a function of years of importation, m. Values for m range between 0 and 50 and are represented on the x-axis.

Figure 2. Probability of Importing BLU-Viremic Cattle Within 50 years



Variability of the results, which also reflects uncertainty, is demonstrated by the 95th percentile line and the corresponding 5th percentile values. The 5th percentile values are 0 for all years and coincide with the x-axis. Therefore, they are not shown separately.

The probability values over 10- and 40-year periods are used to illustrate this variability. After 10 years, the 5th and 95th percentile values are 0 and approximately 0.06, respectively. After 40 years, the values are 0 and approximately 0.214. The variation is relatively large, which suggests a high level of uncertainty.

Effect of Quarantine

For the first 50 years of importation, the simulation results show that the most frequent probability of importing one or more viremic animals is zero, although the mean or expected value is greater than zero for each year. The likelihood of importing a viremic animal, in spite of the low probability of an infected animal remaining viremic after a 60-day quarantine, is explained by the relatively large number of animals (30,000) projected for export from the affected zones.

A point estimate for the expected value of the average number of years before the importing one or more viremic animals is 332 years. However, it should be recognized that this point estimate does not address uncertainty.

The final probability estimated for importation of a viremic animal is greatly influenced by the length of the quarantine period. The quarantine effect is assessed by comparing the probabilities reported after quarantine with those estimated in the absence of a 60-day quarantine period.

Without the 60-day quarantine, the probability of importing one or more viremic animals within a 1-year period is very high. Without quarantine, the mean likelihood of importing a viremic animal is 0.96 in the first year. The 5th and 95 percentile ranges for this value are 0.67 and 1.0, respectively, and indicate a relatively high probability.

As a further comparison, the probability of importing one or more viremic animals within a 2-year period is estimated. This is also very high. The mean probability over a 2-year period is 0.98. The 5th and 95th percentile values are 0.89 and 1, respectively, indicating a very high probability of importing a viremic animal.

Branch Point 4

Branch Point 4 represents the likelihood that disease will be transmitted to U.S. sheep or wild deer after an infected animal arrives at a quarantine facility in the United States. This could occur if, before slaughter, a competent vector were to ingest a blood meal from an animal infected with BLU virus and transmit it to another susceptible animal in the United States. If disease is not transmitted because the level of viremia is insufficient to infect the vector, the number of competent vectors is insufficient, no competent vectors are available, or the Australian serotypes are not naturally pathogenic, risk is negligible. In fact, we were unable to obtain information sufficient to allow us to estimate a probability for these events. However, we did locate and consider information relevant to the issues.

First, our quantitative assessment suggests that some time will lapse before viremic cattle can be predicted to enter the United States. Therefore, the probability that infection will enter the United States any time in the near future is probably low, although there is a high level of uncertainty associated with the quantitative estimates.

Second, if a viremic animal should enter, we predict that the level of viremia will be low, and consequently, the likelihood of disease transmission will be low. This prediction is based on the information provided in the discussion of Branch Point 3 regarding the characteristics and duration of viremia. It has been stated that midges are more likely to ingest threshold levels of virus when titers are high soon after infection (OIE 1998), and the animals will have been subjected to the quarantine. A low level of viremia reduces the likelihood that an infectious dose could be ingested, even if an adequate number or density of competent midges are available.

Therefore, we consider that the level of viremia will be low enough that competent midges will not be infected.

Third, there is the issue of availability of competent midges. Some risk will remain if sufficiently infected animals enter and are exposed to competent vectors in the United States. This can occur only if U.S. vectors are competent to transmit Australian serotypes. We were unable to establish whether this condition applies. No overlap exists between either the vectors or the BLU serotypes in the United States. and Australia, and no epidemiological evidence that U.S. vectors are competent to transmit Australian serotypes was located. However, it does not seem likely that U.S. vectors and Australian BLU serotypes provide a viable combination for disease transmission, since the systems apparently evolved separately. Furthermore, no epidemiological evidence exists for BLU disease being transmitted out of its original ecological niche (Gibbs 1992; Gibbs and Greiner 1994).

If U.S. vectors are able to transmit Australian serotypes, highly competent vectors feeding on animals with low virus titers may be infected with a small amount of BLU virus even toward the end of the viremic period, if competence and attack rate are sufficient (OIE 1998). A highly competent vector can be infected with a small amount of BLU virus. That level may be as low as one infectious unit of virus (OIE 1998). However, there is no reason to assume that a vector-serotype combination would cooperate that efficiently because researchers believe that most such combinations evolved concurrently within a given ecosystem (OIE 1998).

Fourth, even if an infected animal entered the United States and a sufficient number of competent vectors were able to transmit the infection, we consider it unlikely that clinical disease would occur in sheep. This prediction is based on the lack of evidence that Australian BLU serotypes are naturally pathogenic for sheep or wildlife. Infection of wildlife is an issue to consider because BLU is endemic in deer in various parts of the United States (Waldrup et al. 1989; Aguirre et al., 1995). However, there is no more reason to assume that Australian serotypes are pathogenic for U.S. deer than to assume that they are pathogenic for U.S. cattle.

Finally, no historical support exists for movement of BLU in international trade. Gibbs (1992) reviewed the international situation and concluded that there were no substantiated examples of international movement of infected live animals or animal products leading to clinical disease in the importing country.

Assumptions underlying this assessment

1. Despite the lack of clinical signs under natural conditions, BLU serotypes detected in northern Australian cattle are pathogenic for sheep.

2. A viremic animal is capable of transmitting infection, although APHIS has no specific information on the minimum level of viremia necessary to infect competent midges. In fact, OIE

documentation indicates that the infection threshold for a BLU vector is variable. It depends on the genotype of the vector, the genotype of the BLU virus strain, and on the environment. Also, variability in virus assay systems affects assessment of infectious threshold values (OIE 1998).

However, it is reasonable to assume that a minimum level of virus is necessary for disease transmission. It follows that, by the end of the quarantine period, the level of viremia may be reduced to a detectable level but one that is unlikely to infect competent midges. Relevant to this, peak viremias occur in the first 2 to 3 weeks of infection, and serum antibody is detected subsequently. Midges are more likely to transmit disease when the level of viremia is high. After the first 2 to 3 weeks of infection, virus titers drop rapidly and are very low in infections lasting a month or more (OIE 1998).

3. The only viremic animals at the end of the quarantine represent animals viremic upon entering the U.S. import quarantine feedlot. In other words, no new infection occurs during the quarantine period. We assume this because the quarantine restrictions are designed to prevent infection. Moreover, at the end of the quarantine period, the protocol specifies that the animals must be transported in cleaned and disinfected vehicles through a region certified as free of competent vectors to a port of embarkation. This port must be located in a region certified free of midges capable of transmitting BLU. Cattle are then loaded onto a cleaned and disinfected vessel. They are not allowed to come into contact with animals that were not quarantined under the same standards. Because of these restrictions, APHIS considers the risk of an animal becoming infected during exportation to be negligible.

To address the risk of an animal remaining viremic at the end of quarantine, we compare the duration of the quarantine period with the duration of viremia. Data describing the duration of viremia are reported in Table 7 (Appendix G, section I). These data demonstrate that most cattle are viremic for less than 4 weeks. Occasionally, longer periods of viremia are observed. One of the 477 animals assessed remained viremic for a period of 11-13 weeks. Worthy of consideration is that the data for the single animal that was viremic for more than 8 weeks were considered equivocal by the original investigator (Melville, cited in OIE 1998).

Akabane, Aino, and Bovine Ephemeral Fever

Consideration is limited to the mitigated risk of importing these three diseases under the conditions described in the draft protocols (Appendix A). We consider the risk of importing these diseases to be less than the risk of importing BLU. This evaluation is based on the duration of viremia for each infection. The durations of viremia for akabane, aino, and bovine ephemeral fever viruses are significantly shorter than that for BLU. The duration for akabane is 3-5 days (Parsonson et al., 1981; Walton, 1992); the duration for aino is 28 days (McPhee et al., 1986); and the duration for bovine ephemeral fever is reported as less than 5 days (Banks 1999).

We assume that the animals are unlikely to become viremic during quarantine because of restrictions imposed by quarantine provisions. Specifically, AQIS certifies that the pre-embarkation quarantine area is free of vectors that transmit these viruses. Therefore, any animals which remain viremic at the end of the quarantine period were already viremic when they entered quarantine. Because the quarantine period is significantly longer than the duration of viremia for any of these diseases, we consider it to be extremely unlikely that viremic animals will remain capable of transmitting these diseases after quarantine.

Babesiosis

We consider the mitigated risk of importing babesiosis under the conditions described in the protocol to be acceptable. Relevant mitigations include certification of freedom from tick vectors that transmit *Babesia* and a variety of measures intended to eliminate exposure to ticks before, during, or after the quarantine.

Pre-quarantine provisions include use of hay or straw that originates from tick-free regions during shipment and transporting cattle to the quarantine feedlot in cleaned and disinfected vehicles. In addition, stops or transits through vector-affected regions are prohibited.

Protocol provisions relevant to the quarantine itself include AQIS certification that the quarantine area is free of tick vectors that transmit *Babesia*, certification that the port of embarkation is in a region certified free of competent tick vectors, inspection of cattle within 10 days of export for external parasites and treatment with an approved acaricidal product, and inspection of cattle by the port veterinarian.

Post-embarkation provisions require that cattle may only be released from an approved post-entry quarantine for export or to a USDA-approved slaughter plant for immediate slaughter.

As a result of these mitigations, APHIS considers the risk of introducing and transmitting babesiosis to be negligible.

Tuberculosis and Brucellosis

Before generating this report, the disease status of Australia was evaluated with regard to tuberculosis and brucellosis. This evaluation was based on documents submitted by AQIS, including those cited as AQIS 1998 and OIE 1998. APHIS concluded that Australia is free of both diseases. Therefore, APHIS considers the risk of introducing bovine brucellosis and tuberculosis to be negligible.

The rationale for this position is documented in qualitative APHIS risk assessments provided as Appendices B and C.

The risk considered in the assessments for tuberculosis and brucellosis does not include mitigations provided by the 60-day embarkation quarantine, although this is a provision of the protocol for all feeder cattle. Compliance with the 60-pre-embarkation quarantine provides an additional level of mitigation for these diseases.

Transshipment through Mexico

Mitigations relevant to transshipment through Mexico and to direct shipment of animals to the United States are summarized in Appendix F. The same initial provisions apply to animals shipped directly to the U.S. and transshipped through Mexico. These include all of the provisions described in this document.

Additional protocol restrictions apply to animals transshipped through Mexico. Specifically, an official Mexican health certificate is required in addition to the certificate from Australia. Both the Australian and Mexican health certificates must indicate that there has been no interruption in government oversight between the time Australia released cattle to Mexico and Mexico assumed authority. Mexico must provide the following additional certifications: (1) the cattle must have met all health requirements for entry into Mexico and not have been in any country other than Australia and Mexico; (2) the cattle must be identified and traceable to their origin; (3) the cattle must have remained in Mexico for a minimum of 60 days and quarantined for at least 30 days; (4) the cattle must have been inspected by a veterinarian and found free of communicable disease and free of fever ticks: and (5) and dipped in acaricidal dip within 7 to 12 days before presentation at the port of entry.

With respect to babesiosis, cattle shipped through Mexico will be chute-inspected for ticks and dipped in an APHIS-approved acaricide under APHIS supervision. If ticks are discovered, the consignment will be dipped and held at the border for reinspection in 10 days. The process will be repeated until chute inspection reveals no ticks. Additional mitigations that occur once the animals arrive in Mexico are also summarized. These include a requirement for two Mexican health certificates, one of which requires uninterrupted Federal oversight between Australian release of the cattle and Mexico's assumption of authority, and one of which defines provisions for Mexican disease status, animal identification, movement controls, inspection, and quarantine. In this regard, cattle must remain in Mexico for a minimum of 60 days, 30 of which must be in quarantine.

We consider the risk associated with transshipment through Mexico to be no more than, and probably less than, the risk associated with direct shipment to the United States. The additional quarantine period required in Mexico provides a further mitigating influence, and no additional risk should be encountered for any of these diseases for these reasons:

1. The BLU serotypes are the same as those occurring in the U.S. (Gibbs and Greiner 1994).

2. Aino, akabane, and bovine ephemeral fever do not occur in Mexico.

3. The same babesiosis mitigations deemed acceptable for Australia also apply to Mexico.

4. Protocols for export of cattle from Mexico to the United States specify unique mitigations for tuberculosis and brucellosis.

Limitations of the Assessment

One limitation associated with this assessment is the uncertainty regarding the assumption that a viremic animal is equally infective throughout the entire duration of viremia. APHIS considers it unlikely that infectivity is equivalent throughout the entire period. Acceptance of this assumption may result in overestimation of the risk.

A second limitation is the potential for overestimation of variability, which is explained in Appendix G, section III.

A third limitation is the uncertainty about extrapolations of the duration of viremia data in Table 7 (Appendix G, section I: Conversion of Incidence to Prevalence) to points up to 140 days. Table 7 contains one observation of a 12 week (84- day) duration of viremia and nothing beyond this point. Without direct evidence, fitting a curve to Table 7 data with a reasonable fit based on our best judgment was considered an appropriate method to obtain probabilities beyond 84 days.

APPENDICES

A - Protocol for the Importation of Feeder Cattle from Australia - Draft Dated February 11, 2000.

B - Risk Assessment: Bovine Brucellosis in Australia, June, 1999

C - Risk Assessment: Bovine Tuberculosis in Australia, June, 1999

D - ABC News Brief on Cattlemen's Association, August 26, 1998

E - Qualitative Risk Assessment: Bluetongue Virus Distribution in Australia, September, 1999

F - Protocol for the Importation of Feeder Cattle from Australia Through Mexico - Draft dated February 11, 2000

G - I. Conversion of Incidence to Prevalence
II. Stage of Viremia
III. Estimation of Joint Probabilities

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